

REMARKS

Claims 1; 2; 3; 4; 5; 7; 8; 9; 10; 11; 12; 13; 14; 15; 17; 18; 19; 20; 22; 23; 24; 25; 26; 27; 28; 30; 35; and 39 have been amended. Claim 21 has been canceled. New claims 40 to 52 have been added.

Claims 1 to 20 and 22 to 52 remain in the application. Of these, claims 1; 8; 10; 31; 40; 41; 42; 43; 44; and 45 are independent apparatus claims. Claims 30; 39; and 52 are method claims dependent upon independent apparatus claims.

Reexamination and reconsideration are respectfully requested in view of these amendments and the following remarks.

The Examiner has indicated that claims 11; 12; 21 to 24; 27 to 29; and 31 to 39 are allowable if placed in independent form. The claims have been amended to place these claims in independent form and condition for allowance (it is noted that claim 31, as filed, was an independent claim). Claims 35 and 39 have been amended to correct a typographical error. Method claims 30 and 39 have been amended to add “comprising” at the end of the preamble.

More particularly:

(i) New independent claim 43 places original claim 11 in independent form by incorporating the subject matter of original independent claim 10 and dependent claim 11

(ii) New independent claim 44 places original claim 12 in independent form by incorporating the subject matter of original independent claim 10 and dependent claim 12.

(iii) Amended independent claim 1 incorporates the subject matter of multiple dependent claim 21/1 – thereby placing original claim 21/1 in independent form (a typographical error has also been corrected). Original claim 1 has been further amended by changing the terminology “a tissue region in a lateral pharyngeal wall” to “a tissue region in a pharyngeal wall.” Dependent claims 3 and 7 have been amended to reflect this change in terminology. Applicant believes that his change in terminology does not

alter the indicated allowable status of claim 1 as now amended to incorporate dependent claim 21(1).

(iv) Amended independent claim 8 incorporates the subject matter of multiple dependent claim 21/8 -- thereby placing original claim 21/8 in independent form (a typographical error has also been corrected). Consistent with the foregoing amendment to claim 1, the terminology "a lateral pharyngeal wall" found in original claim 8 has been changed to "a pharyngeal wall." Applicant believes that his change in terminology does not change the indicated allowable status of amended claim 8 as now amended to incorporate dependent claim 21/8.

(v) Amended independent claim 10 incorporates the subject matter of multiple dependent claim 21/10 -- thereby placing original claim 21/10 in independent form (a typographical error has also been corrected).

(vi) New independent claim 40 incorporates the subject matter of multiple dependent claim 27/1 -- thereby placing original claim 27/1 in independent form (a typographical error has also been corrected). Consistent with the foregoing amendment to claim 1, the terminology "a tissue region in a lateral pharyngeal wall" found in original claim 1 has been changed to "a tissue region in a pharyngeal wall." Applicant believes that his change in terminology does not change the indicated allowable status of new claim 40 as now amended to incorporate dependent claim 27/1.

(vii) New independent claim 41 incorporates the subject matter of multiple dependent claim 27/8 -- thereby placing original claim 27/8 in independent form (a typographical error has also been corrected). Consistent with the foregoing amendment to claim 8, the terminology "a lateral pharyngeal wall" found in original claim 8 has been changed to "a pharyngeal wall." Applicant believes that his change in terminology does not change the indicated allowable status of new claim 41 as now amended to incorporate dependent claim 27/8.

(viii) New independent claim 42 incorporates the subject matter of multiple dependent claim 27/10 -- thereby placing original claim 27/10 in independent form (a typographical error has also been corrected).

(ix) New independent claim 45 is based upon original dependent claim 36 (dependent upon original claim 31) -- which were each indicated as being allowable -- except that the terminology "at least two discrete sources of magnetism" in original claim 31 has been changed to "at least one discrete source of magnetism having a periphery" and the terminology of original claim 36 has been further changed to define a flexible polymer matrix that includes a protective material encapsulating the source of magnetism and an edge region extending beyond the source of magnetism to allow flexure of the flexible polymer matrix relative to the source of magnetism. New dependent claims 46 to 52 incorporate the subject matters of original dependent claims 32; 33; 34; 35; 37; 38; and 39, respectively.

(x) The dependencies of original dependent claims have been made multiple dependent to reflect the amended and new independent claims.

The Examiner's time and attention during an interview on August 16, 2006, is appreciated. Present at the interview were Nat Bowditch (President and CEO of Apneon Inc., the assignee of the instant application); Andrew Kramer (Vice President, Research and Development of Apneon Inc.); Gabriela B. Tomescu, Esq. (Counsel & Intellectual Property Coordinator of Apneon); Ryan Boucher (a product engineer of Apneon Inc. and one of the inventors named on the instant application); and the undersigned patent counsel for Apneon. Prior to the interview, applicant submitted a draft amendment of the claims. During the interview, draft claims 43 to 45 were discussed, as was Freedman US 5,176,618 (Freedman). The Examiner suggested an amendment to draft claim 44 as a matter of clarification. In discussions with the Examiner related to Freedman, the applicant also suggested an amendment to draft claim 45. The applicant has incorporated these amendments in this formal submission of Amendment A.

During the interview, Nat Bowditch discussed (with the aid of a Power Point® presentation) the clinical treatment of obstructive sleep apnea (OSA), which currently afflicts about 18 million Americans. Nat Bowditch discussed the serious consequences of OSA, including the higher mortality rate of people afflicted by OSA when left untreated. Nat Bowditch also discussed the current treatments for OSA, namely Continuous Positive

Airway Pressure (CPAP); maxillomandibular advancement (MA); uvulopalatopharyngeoplasty (UPPP); and oral appliances. Nat Bowditch explained the problems with CPAP, including a high incidence (up to 65%) of non-compliance or discontinuance, as well as complaints of noise, nasal congestion, gum problems, discomfort, claustrophobia, and dry nose/mouth. Nat Bowditch also discussed the problems with MA, including the highly invasive natures of the surgical procedures, the long recover time, and low patient appeal. Nat Bowditch further discussed the limited success rates of UPPP and oral appliances.

The structure shown in Figs. 3 and 4 of Freedman, and the corresponding description found in Freedman column 7, lines 9 to 28, were discussed with the Examiner. As set forth during the interview, it is applicant's position that Freedman discloses use of a rigid implant for the concentration of force, including wings that extend the contact region of the rigid implant. As set forth during the interview, it is applicant's position that Freedman does not teach or suggest an implant device that includes at least one source of magnetism having periphery and a flexible polymer matrix that includes a protective material encapsulating the source of magnetism and an edge region extending beyond the source of magnetism to allow flexure of the flexible polymer matrix relative to the source of magnetism. It is the inclusion of this subject matter into draft claim 45 that was suggested by the applicant during the interview. This language has been incorporated in new claim 45 as now formally submitted.

With the aid of models and representative implant devices, Ryan Boucher explained the discovery that stiff or rigid magnetic implants, like those shown in Freedman, are less likely to be tolerated by the body. Ryan Boucher discussed the discovery of imparting flexibility along the edge of an implant, as now defined in new claim 45, which prevents foreign body sensation and the concentration of force that can lead to extrusion from the tissue, as well as provides an implant that does not interfere with normal functions such as speech and swallowing.

At the conclusion of the interview, after the proposed amendments to claims 44 and 45 were discussed, the Examiner indicated that agreement was reached and that the

proposed amendments to claims 44 and 45 (now incorporated in new claims 44 and 45 as submitted in this formal Amendment A) appear to define over Freedman and place the application in condition for allowance.

During the interview, the undersigned patent counsel indicated that there are examined companion cases assigned to Apneon that are generally directed to the placement of various magnetic implants in regions of the body such as the tongue, soft palate, and oral cavity, albeit not in a flexible polymer matrix. These examined companion cases are:

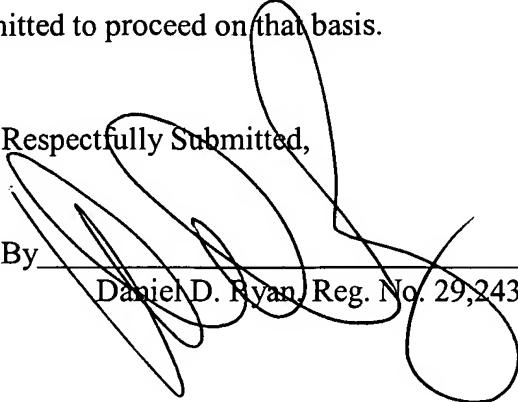
- (1) Application Serial No. 10/236,455, pending before Examiner Michael A. Brown, Group Art Unit 3764, Notice of Allowance Mailed August 29, 2006.
- (2) Application Serial No. 10/236,297, now US Patent No. 6,955,172.
- (3) Application Serial No. 10/236,454, now US Patent No. 7,073,505.

The undersigned patent counsel indicated, for the sake of good order, his intention to submit a Supplemental Information Disclosure Statement in this case, which cross references the documents of record in these companion cases, to the extent that have not already been cited in the instant case. The Supplemental Information Disclosure Statement, with copies of the documents, accompanies this Amendment. The Supplemental Information Disclosure Statement also lists US 5,019,372 and DE 43 07 262 (with an English Abstract), which were cited in a European Search Report for the European counterpart of a pending unexamined application assigned to Apneon; namely, Application Serial No. 10/806,372, pending in Art Group 3732 (Examiner not yet assigned). The Supplemental Information Disclosure Statement also lists Published Patent Application Brooks et al. US 2004/0112390 (magnetic implants placed in an airway); Knudson et al. US 7,077,143 and US 7,077,144 and US 6,636,767 (non-magnetic implants placed in an airway); as well as US Patent No. 6,955,172 and US Patent No. 7,073,505 (the issued Apneon companion patents identified above).

Claims 1 to 20 and 22 to 52 are believed to be in condition for allowance. If the Examiner believes that questions or matters of clarification remain, which can be handled expeditiously by an interview, either in person or by telephone, to advance prosecution of this case, the applicant remains committed to proceed on that basis.

Respectfully Submitted,

By


Daniel D. Ryan, Reg. No. 29,243

RYAN KROMHOLZ & MANION, S.C.
Post Office Box 26618
Milwaukee, Wisconsin 53226
(262) 783 - 1300
Customer No.: 58633